REMARKS

Claims 1-15, 51, 52, and 56-64 are pending in the application. Claims 59-64 are new claims.

New claims 59-61 replicate the limitations of claim 13 and clarify that the subject seeds, for example, those of the ATCC deposit have a distribution of color that falls within the claimed color range. This distribution is an inherent property describing the seeds on deposit, and as such is properly claimed. New claims 62-64 replicate the limitations of claim 13 and clarify that the subject seeds, for example, those of the ATCC deposit contain germplasm capable of providing a distribution of color that falls within the claimed color range.

1. *Reissue Format Claims*

The Office observes that the claims provided with the response to office action on March 25, 2003 were not presented in a proper reissue format. The Amended Claims submitted with this response are marked up for cumulative amendment with respect to the issued claims, as per 37 C.F. R. §1.173.

2. *Offer to Surrender*

The Office Action requires an actual surrender of the original patent grant and advises that this reissue housekeeping duty may be deferred until the time of allowance.

3. *Drawings.*

The Patent Owner appreciates entry of the drawings filed 3/25/03.

4. *Third Party Protests.*

It appears that the documents filed by third parties in this proceeding have been treated as protests and afforded full consideration. The Patent Owner appreciates that the Office has made an extra effort to consider those submissions when it is not required to have done that, and thanks the Office for doing so. In line with the consideration that has occurred, we would like to observe for the record that the Office does not normally consider third party arguments in a proceeding of this type, especially where Dr. John Dodds represents CIAT, which is the party requesting reexamination. This type of practice converts the consolidated reexamination proceeding into a *de facto interparties* proceeding

when the proceeding is technically on an *ex parte* basis. Although an *interparties* proceeding may be requested under the present rules, there is a significant difference in that the results of an *interparties* proceeding become legally binding and cannot be challenged in subsequent litigation. We expect that due weight will be given in litigation for the *interparties* proceeding that has, in fact, occurred.

5. Objections

The Patent Owner appreciates the withdrawal of objections to claims 15, 55 and 58.

6. Rejection

The Patent Owner appreciates the withdrawal of the 35 U.S.C. §112 ¶ 2 rejection of claims 7, 9, 54, and 56.

8-9 *Information Disclosure Statement*

Please find an Information Disclosure Statement attached to include the references cited on the face of US 5,984,079 (TAB 1). It is noted that the Office has lined through various translation documents indicating they have not been considered or are unsuited for publication. In some cases, these are translations of foreign language documents that are already of record. In other cases, these are documents that pertain to litigation involving the patent at issue. In other cases, these have been provided with documents that have been treated as protests and are also of record. We urge the Office to consider any such materials that it may find to be relevant and/or material to examination.

The Patent Owner is concerned that other IDS materials do not seem to be acknowledged by the Office. Attached is a listing of materials provided and a PAIRS report (TAB 2) showing receipt by the Patent Office of Information Disclosure Statement (IDS) materials on 6-04-2002 and 2-12-2002 in reexamination proceeding 90/005,892, but there are no corresponding entries in reissue proceeding 09/773,303. Attached to this response are cumulative copies of the forms 1449 (TAB 3) that should be of record in the present proceeding. We ask the Office to indicate whether each reference has been considered, to the extent that the examiner has not already initialed the reference as being considered.

10. Oath/Declaration

A replacement Declaration is attached (TAB 4). This Declaration is intended to

replace the Declaration filed with the original application, and reflects the status of the claims as originally filed. The Declaration identifies Larry Proctor as "the sole inventor," whereas the original Declaration identifies him as "the named inventor." The replacement declaration specifically identifies new claims 16-58, whereas the original Declaration identified only "new claims." A detailed discussion is provided in each instance documenting the nature of broadening where the error is, as stated in the original Declaration, that the original patent claimed less than it was entitled to claim.

We respectfully traverse the finding that the original Declaration does not identify Larry Proctor as the "sole or joint" inventor, because the signature block thereof clearly identifies him as "sole inventor." We respectfully traverse the finding that the original Declaration does not identify one specific error that is relied upon to support the reissue application. This is for a number of reasons. First, Rule 175 nowhere states a requirement to identify a "specific error"—the Rule says "stating at least one error." This was done in the original Declaration where "Reference is made to new claims added to this patent." The replacement Declaration identifies these new claims and the nature of the broadening with increased particularity, and is also in compliance with Rule 175.

The Patent Owner does not believe that the issued claims are defective for the patentee having claimed more than the patentee has the right to claim; however, the Declaration also alleges a desire to have a complete examination on the basis of newly cited art, as is commensurate with the scope of a combined reissue/reexamination proceeding.

11. Election/Restriction

Claims 16-50 and 53 are withdrawn from consideration, noting that Applicant has not canceled these claims. The Patent Owner appreciates the explanation of constructive election provided by the Office.

12. Claim Objections

Phaseolus vulgaris is now italicized in the claims. It will be appreciated that the term was italicized in the originally issued claims and is shown as such in the accompanying replacement claims of Appendix A. This amendment is made as a matter of form over

substance and not for any reason related to patentability.

13. Claim Rejections 35 U.S.C §112 First Paragraph Written Description

Claims 1-15, 51, 52 and 56-58 stand rejected under 35 U.S.C. §112 first paragraph. We respectfully traverse and request clarification.

Clarification is needed to define the nature of this rejection. This is because the Office does not cite authority providing a basis or analytical framework to determine whether the requirement is satisfied. The Office on page 4 states a requirement that the specification must describe the invention in "such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." It is unclear whether the rejection is generically based on written description, or particularly with respect to possession. Suppose generally we read the rejection as being stated for lack of possession; however, if this is the case the Office does not identify a basis or framework recognizing how written description may be satisfied. The Federal Circuit has enunciated one such standard in *Lockwood*, which we presume to be the applicable test:[1]

> Lockwood argues that all that is necessary to satisfy the description requirement is to show that one is "in possession" of the invention. Lockwood accurately states the test, *see Vas- Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), but fails to state how it is satisfied. One shows that one is "in possession" of the invention by describing the *invention*, with all its claimed limitations, not that which makes it obvious. *Id.* ("[T]he applicant must also convey to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*.") (emphasis in original). One does that by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention. Although the exact terms need not be used *in haec verba*, see *Eiselstein v. Frank*, 52 F.3d 1035, 1038, 34 USPQ2d 1467, 1470 (Fed. Cir. 1995) ("[T]he prior application need not describe the claimed subject matter in exactly the same terms as used in the claims.. . ."), the specification must contain an equivalent description of the claimed subject matter.

The Office has not made a showing commensurate with *Lockwood* requirements or those of other authority, and so does not state a *prima facie* case for the rejection. Under

[1] *Lockwood v. American Airlines Inc*, 41 USPQ2d 1961 (Fed. Cir. 1997).

Lockwood, the specification must contain an equivalent description of the claimed subject matter, for example, as may be provided "by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention." In the present specification, this is done by an exacting discussion of plant morphology and selection processes, together with an ATCC deposit of the germplasm. Here the Office too narrowly characterizes the ATCC deposit of record, which is biological material that may be used and applied as taught by the Specification within the level of ordinary skill to develop a number of different cultivars. See for example the Abstract, which teaches crossing of the cultivar on deposit. *See* US 5,894,079 in column 6 at lines 9-12 for the deposit.

This deposit forms part of the written description and may alone be sufficient to meet the written description requirement. As determined in *Enzo Biochem Inc. v. Gen-Probe Inc., 63 USPQ2d 1609 (Fed Cir. 2002)*:

> While the district judge clearly understood and correctly applied this court's existing precedent, we nevertheless reverse because this case has taken us into new territory and we have held, as a matter of first impression, that reference in a patent specification to a deposit of genetic material may suffice to describe that material. We therefore remand for further resolution consistent with this opinion.

Furthermore, it is also permissible to use the deposit of record for what it inherently shows. This deposit may be claimed according to the description of properties that are inherent to the deposit, even if those properties are not fully disclosed *in haec verba* in the original specification. *In re Nathan*, 328 F.2d 1005, 1008-1009, 140 USPQ 601, 604 (CCPA 1964) (the court holding that a later-added limitation to the claims of the compound's alpha orientation was "an inherent characteristic" of the claimed subject matter to reverse a new matter rejection); *see Kennecott Corp. v. Kyocera Int'l, Inc.*, 835 F.2d 1419, 1421, (Fed. Cir. 1987) (holding that the disclosure in a subsequent patent application of an inherent property of a product does not deprive that product of the benefit of an earlier filing date because the addition is not new matter). Therefore, it is appropriate that new claims 59-64 describe inherent properties of the ATCC deposit.

The Office finds that certain statements and showings of record conflict with statements that the Patent Owner made in the patent disclosure. We strongly disagree with that position because there is no such conflict. The Office asserts that the Conley declaration filed 3/25/03 shows individuals 1, 51 and 52 are compared and shown to differ using multiple AFLP markers. Furthermore, the Office finds that Applicant has described the ATCC deposit as including a variety of genetic entities with a range of sizes, shapes, and colors, both of seed coat and of hilar ring. The plants and pods also show a diversity of selectable traits within narrow ranges. There is no contradiction here, as the showing of record is in harmony with the specification and the definition of cultivar. Although the Office would impose a standard of genetic perfection and identity, there is no such thing in this art.

The Office asserts that the Specification describes the Enola bean as a "cultivar," which is a term well understood in the art to mean a "*genotypically and phenotypically homogenous* [emphasis added] population of plants." In another place, namely, point 14 on page 13 of the current office action, the Office also asserts that "[t]he purpose of deposit seed is to provide a reproducible means of making a *genetically and phenotypically unique* plant that cannot be recreated based on a patent disclosure." The Office is using an arbitrary concept of genetic and phenotypic uniqueness or homogeneity for two ends, namely to define a cultivar and to assert the legal purpose for making a seed deposit. The Office does cite authority for those assertions. We traverse and insist upon the Office providing a reference to support both positions.

We fail to understand the relevance of this semantic dispute. Where the claims define the invention, the word "cultivar" does not appear in the claims. Therefore, the term is irrelevant to written description analysis and should not be read into the claims in support of this rejection. Assuming, arguendo, in an academic excursion that the term is relevant, the Patent Owner objects where the Office has not provided a reference for the applied definition of "cultivar." The definition now applied by the Office differs from a range of other accepted meanings to impose unwarranted requirements where, for example, Webster's Ninth New Collegiate Dictionary defines cultivar as "an organism of a kind originating and persistent under cultivation." This does not require genotypic and phenotypic homogeneity.

A "cultivar" may also be alternatively defined as "a variety of plant originating from a natural species and maintained under cultivation" or "a cultivated plant or animal that has no known wild ancestor." *See* attached "hyperdictionary" printout (TAB 5). "Cultivar" has a variety of meanings.

Enola is a cultivar, for many years been a persistent cultivar that is sold on a large commercial scale, and is recognized as a cultivar by the art in wide-ranging publications. The passage of the disclosure quoted by the Office to show uniformity and stability of the Enola phenotype on deposit is correct. Other evidence and remarks of record do not contradict what is disclosed. The Declaration of Gil Waibel (TAB 6) shows that Enola is persistent and uniform under cultivation where there is a comparison between Enola breeder seed lots from 1996 and 2001 crop years, Enola certified 2001 seed lots, and infringing Yellow River seed from crop years 2001 and 2002. Thus, the Waibel Declaration entails a comparison of Enola for crop years 1996, 2001 and 2002, with the infringing Yellow River seed.

The Office attempts to show that Enola is not a cultivar as described in the specification. That finding is easily rebutted. The Office observes that the Specification shows the cultivar has been increased with continued observation for uniformity, and that no variant traits have been observed or expected in Enola. The Office refers to the Declaration of Larry Proctor filed 3/25/03 for further statements to this effect—showing selection for stability and improvement to develop Enola. With this evidence of stability, the Office finds that some evidence in a small sample of AFLP markers is *not* clear evidence of a widely variant population of plants with a multitude of genetic bases for yellow seed coat color, as well as diversity of other plant characteristics. Thus, the Office contradicts its own finding that there is impermissible wide-ranging genetic variation within the Enola cultivar. The Office then asserts, partly on the basis of evidence it disputes, that the Patent Owner has not satisfied written description for the broadly claimed invention.

The Patent Owner does not necessarily assert that there is or is not wide ranging genetic variation within the cultivar. Enola is a cultivar because it is persistent under cultivation. It is also a variety (see Abstract) because the plants are distinguished from

other plants by common characteristics or qualities. These common characteristics and qualities are uniform and stable as described by the Specification and confirmed by the Declaration of Gil Waibel. It is possible that the observed characteristics and qualities, i.e., traits (the Office broadly uses the word phenotype) come from one or more genetic bases; however, regardless of genetic uniformity, there is uniformity and stability of the observed traits or phenotypes.

It is the nature of this art that new cultivars are commonly developed by selection processes from a milieu of germplasm that may constitute a plurality of individual plants, each having a unique genetic makeup. The native or parent germplasm is selected and refined by well-known breeder-grower selection processes to reinforce and encourage selected desirable traits or phenotypes. By this process, part of the milieu is shown to be refined by selection when the cultivar is uniform and stable, and such is the case for Enola.

The definition applied by the Office is contrary to accepted meaning in the art where, for example, there are well-documented instances of in-cultivar genetic variations. This is why it is appropriate for the Specification to observe, as it does in the passage quoted by the Office, that no variant traits of Enola have been observed or are expected.

Each individual within a cultivar may have a unique genetic makeup—even where all members of the cultivar share uniform and stable traits or phenotypes that are persistent under cultivation. The passage of the Specification quoted by the office as indicating that Enola is uniform and non-variant affirms generally the average values of morphological traits or phenotypes under the growout conditions in the remarks following that passage. The passage is also an indication that the self-segregating population of plants observed in the initial growout (column 3, lines 3-7) is not known to occur in the cultivar. Therefore, the ATCC deposit is of itself a genus of cultivar comprising individual species or individuals of the cultivar. This does not mean that the cultivar lacks uniformity or stability under ordinary cultivation. In fact, Enola on deposit is extraordinarily uniform and stable, which are reasons for its commercial success.

Naturally selected cultivars are not clones. The Office would require precise

genotypic and phenotypic invariability in the natural reproduction of a cultivar. For example, this would occur by cloning to produce exact copies so that there is no genetic variation. That is not what is practiced in this art where, for example, visual observations are used to select plants for reproduction processes to encourage desired traits. That is the simple process to improve the cultivar and refine the genetic milieu. The task is easy when the selectable traits are taught, for example, as in the present disclosure, especially when the germplasm for the selectable traits is made available by ATCC deposit.

All breeder-selected cultivars contain a milieu of genetic material and it is from this milieu that breeder selection is used to reinforce desired traits or phenotypes. The milieu is refined by breeder selection to create a population that is uniform and stable in the desired characteristics under cultivation. Since that is the way the art works, the definition as used by the Office is contrary to accepted meaning and practice because the Office would require complete identity of genotype *and* phenotype. If, for example, the definition applied by the Office were true, it would never be possible to further improve a cultivar by process of continuing selection. These are not clones and it is enough that they demonstrate uniform and stable traits. The RFLP evidence documented in the Conley declaration filed 3/25/03 is merely evidence of genomic differences to show these are individual plants. It is significant that the alleles indicated by RFLP are not shown to be linked to phenotypic diversity.

Experience has shown it to be invariably the case that Enola stably and uniformly replicates the described traits or phenotypes when left to grow without interference from the hand of man. The differences observed by the Office are small variations to a matter of degree in the selected traits, which do persist under cultivation. The Declaration of Gil Waibel filed with the response on 3/25/03 (also TAB 6) shows comparative differences as might be expected from a uniform and stable cultivar in a direct comparison spanning crop years 1996 to 2002.

There is substantial evidence of record to show Enola persistence and/or uniformity. The Declaration of Gil Waibel compares a variety of trait assessments plants grown using seed from crop years 1996, 2001 and 2002. Seed color uniformity is especially evident, for

example, in each of charts 15, 31, and 47, which all show a seed coat color distribution in the test population with a peak or mode value precisely as claimed in the Munsell range of from about 7.5 Y 8.5/4 to about 7.5 Y 8.5/6 when viewed in natural light. The Office has quoted a section of the Specification to show that Enola does not have variant traits, but the passage should not be read out of context where these are statistically "average" values, for example, as shown at:

column 3, line 58 (average caliper size of root below the soil line);

column 3. line 67 (average tap root caliper size);

column 5. line 3 (average height of mature plant); and

column 5, line 29 (average break length of pod).

Webster's defines "phenotype" as "the visible properties of an organism that are produced by the interaction of the genotype and the environment." Variations of the kind described in the stable Enola phenotype are commensurate with all other evidence of record when it is considered that plants interact with their environment to produce a phenotype.

The Office describes Myasi, "[a]lthough not available as prior art, the existence of the 'Myasi' bean, which is genetically distinct from Enola, but phenotypically indistinguishable with respect to seed coat color."[5] Those facts have not been shown. It is, for example, possible that Myasi is Enola or was bred from Enola to achieve the seed coat color. Myasi is also comprised of individuals each having a unique genetic makeup, yet they share a common color trait with respect to each other and with respect to Enola. This does not mean that the trait is irreproducible, indescribable, not possessed, or overly broad—in fact the trait is just the opposite of all these things in either cultivar.

We respectfully submit that the Office continues to misapply *University of California*. It is a serious substantive issue that the Office must duly consider and rectify. The Office disagrees with the Patent Owner's assessment that the holding of the *University of California* decision arose significantly from prior law involving cDNAs, and is best viewed in

[5] Office action of December 2, 2003, page 21.

that context. The Office continues to hold *University of California* in high regard and takes exception to the Patent Owner's remarks:[6]

> The holding is broadly applicable to any type of invention, and has been applied widely across the examining corps. at the United Sates Patent and Trademark Office. There is absolutely no basis for interpreting the University of California decision as being so limited.

We agree that *University of California* is widely used in the Patent and Trademark Office. The Office is wrong to do so, and the case is widely misused. *University of California* has been distinguished, explained, clarified, and at least partially overruled, such that the case can no longer be used as presently applied by the Office:[7]

> "Naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further the court held that to adequately describe a claimed genus, patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of members of the genus.

The above passage that the Office quotes from *University of California* is out of context in that it is preceded by a discussion of functional language and followed by a discussion of cDNA. The passage is clearly commenting on the use of functional language to describe cDNA by what it does:[8]

> The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. *See In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). *Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material* [emphasis added].
>
> Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but

[6] Office Action of December 2, 2003, page 7.

[7] Office Action dated September 25, 2002, page 14.

[8] *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

> requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA.

The passage applied by the office is shown in italics above, but the Office omits the word "accordingly"—according to the use of functional language which is not present in the claims now under rejection. These are precisely points that other Federal Circuit cases have distinguished, explained, overruled and/or clarified. Since the Office continues with *University of California*, it seems necessary to educate the Office as to the current status of that case, particularly as applied to the facts of and relevant art of Enola. *University of California* has been distinguished or limited time and again. *University of California* is contrary to later decisions including *Moba*, from which the following passage is taken to show that *University of California* is distinguished and clarified:[9]

> The second application of the written description requirement is reflected in *Regents* of the *University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). There, this court invoked the written description requirement in a case without priority issues. Invoking §112, *Lilly* required a precise definition of a DNA sequence in the patent specification. In more recent cases, however, this court has distinguished *Lilly*. For instance, in *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002), neither the specification nor the deposited biological material recited the precise "structure, formula, chemical name, or physical properties" required by *Lilly*. *Id.* at 1324 (quoting Lilly, 119 F.3d at 1566). Although this court initially determined that the specification in *Enzo* did not satisfy the *Lilly* disclosure rule, it revisited the issue and remanded to the district court. The court instructed:
>
> > On remand the court should determine whether a person of skill in the art would glean from the written description, including information obtainable from the deposits of the claimed sequences, subsequences, mutated variants and mixtures sufficient to demonstrate possession of the generic scope of the claims.
>
> *Enzo*, 296 F.3d at 1328. Similarly, in this court's most recent pronouncement, it noted:
>
> > More recently, in *Enzo Biochem*, we clarified that *Eli Lilly* did not hold that all functional descriptions of genetic material necessarily fail as a matter of law to

[9] *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1320, 66 USPQ2d 1429, 1438-1439 (Fed. Cir. 2003)

> meet the written description requirement; rather, the requirement may be satisfied if in the knowledge of the art the disclosed function is sufficiently correlated to a particular, known structure. *Amgen*, 314 F.3d at 1332.

Enzo and *Moba* affirm that the applicant or patent owner very well may name a type of material generally known to exist since, for example, functional descriptions of genetic material do not necessarily fail. *Moba* has established a different test, namely, "whether a person of skill in the art would glean from the written description, including information obtainable from the deposits of the claimed sequences, subsequences, mutated variants and mixtures sufficient to demonstrate possession of the generic scope of the claims." This is not a bright line rule to require "a precise definition of a DNA sequence in the patent specification."

The Patent Owner has fully met this "possession" test. The deposit speaks for itself in support of claims referencing the deposit where the inherent properties of the deposit are confirmed by the Declaration of Gil Waibel. As regards to the other claims at issue, such as claim 13, "[s]eed from a field bean variety of *Phaseolus vulgaris* that is completely yellow in color, wherein the yellow color is from about 7.5 Y 8.5/4 to about 7.5 Y 8.5/6 in the Munsell Book of Color," these do not recite functional language and so do not encounter the rule of *University of California*, as distinguished by *Enzo* and *Moba*. The total evidence submitted by Applicants, including the specification, the deposit, contemporaneous art, and the expert Declaration of Gil Waibel, repeatedly demonstrates that people with ordinary skill in the art are in possession of what is claimed as measured by the teaching in the disclosure.

The Office finds that *University of California* is not limited to cDNA. In fact, peculiar law that is limited in applicability to cDNA formed the singular narrow basis for the *University of California* holding[10]

> Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention. *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966. We had previously held that a claim to a specific DNA is not made obvious by mere knowledge of a desired protein

[10] *University of California v. Eli Lily and Co.*, 119 F.3d 1559, [redacted], 43 USPQ2d 1398, 1405 (Fed. Cir. 1997).

> sequence and methods for generating the DNA that encodes that protein. *See, e.g., In re Deuel*, 1 F.3d 1552, 1558, 34 USPQ2d 1210, 1215 (1995) ("A prior art disclosure of the amino acid sequence of a protein does not necessarily render particular DNA molecules encoding the protein obvious because the redundancy of the genetic code permits one to hypothesize an enormous number of DNA sequences coding for the protein."); *In re Bell*, 991 F.2d 781, 785, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993). Thus, *a fortiori*, a description that does not render a claimed invention obvious does not sufficiently describe that invention for purposes of Section 112, Para. 1. Because the '525 specification provides only a general method of producing human insulin cDNA and a description of the human insulin A and B chain amino acid sequences that cDNA encodes, it does not provide a written description of human insulin cDNA.

The foregoing passage shows that the Federal Circuit felt constrained in 1997 to follow earlier precedent, namely, that a known protein sequence does not render obvious the cDNA capable of expressing that protein. Even where the specification described the human insulin amino acid sequence but did not disclose the cDNA sequence, earlier precedent constrained the court, *a fortiori*, to invalidate claims reciting functional language that was unsupported by the specification, i.e., "since that which does not render obvious cannot satisfy §112 ¶ 1." To gain a feel for what the Federal Circuit presently thinks of *University of California* see, for example, Judge Rader's concurring opinion in *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1320, 66 USPQ2d 1429, 1438-1439 (Fed. Cir. 2003). The Judge is scathingly hostile to *University of California* (here called *Lilly*):

> In sum, the *Lilly* rule is not just a mere one-time mistake. It defies over thirty years of case law. It finds no specific support in any statutory language. It creates a technology-specific rule in a technology-neutral statute. It distorts the statute's rules for adequate disclosure of inventions. It complicates biotechnology patent drafting to the point of near impossibility and invites invalidating mistakes. It prices non-corporate inventors out of some biotechnological invention markets. Last, but not least, it burdens both trial and appellate courts with unnecessary and confusing procedures in otherwise simple cases like this one.

Judge Rader criticizes the very rule that is presently applied by the Office.

The present art distinguishes *University of California* where breeder selection growers select on the basis of observed phenotypes. This type of selection process is never strictly burdened by genetic sequence requirements. If a breeder so chooses, he or

she may identify one phenotype for selection. There is no analogous sequence to constrain the present art.

University of California is distinguished for other reasons. There the patent claimed, for example, cDNA capable of expressing human insulin. This was a use of functional language to describe the cDNA by what it does, not what structure produces the result. Subsequent Federal Circuit decisions including *Moba* above have clarified *University of California* to show that the use of functional language is reviewed under PTO guidelines, such that the rigor of the standard varies with advancement in the art. See *Enzo Biochem*:[11]

> In *Eli Lilly*, we concluded that a claim to a microorganism containing a human insulin cDNA was not adequately described by a statement that the invention included human insulin cDNA. *Id.* at 1567, 43 USPQ2d at 1405. The recitation of the term human insulin cDNA conveyed no distinguishing information about the identity of the claimed DNA sequence, such as its relevant structural or physical characteristics. *Id.* . . . The specification in the *Eli Lilly* case thus did not show that the inventors had possession of human insulin cDNA.
>
> It is not correct, however, that all functional descriptions of genetic material fail to meet the written description requirement. The PTO has issued Guidelines governing its internal practice for addressing that issue. . . . the PTO has determined that the written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." Guidelines, 66 Fed. Reg. at 1106 (emphasis added).

Thus, it is error to assert *University of California* precludes naming something without precise structure, since a description of characteristics may suffice. It is commensurate with the breeder selection art that characteristics, e.g., the trait or traits being selected or appearing in the plants or seed, are what is described and claimed. *University of California* is limited to the use of functional language pertaining to cDNA as distinguished or overruled by *Enzo* under the better rule of *Moba*.

University of California is still further distinguished where functional language is

[11] *Enzo Biochem Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 63 USPQ2d 1609, 1613 (Fed. Cir. 2002);

presently lacking, except as to claim 62. Claim 62 is asserted to take advantage of the *Enzo* distinction for functional language, as recognized by *Moba*. Functional language differs from the express structural language and characteristics that are presently claimed. Where functional language is used, as distinct from structural language or characteristics, the analysis devolves to one in which the primary inquiry is to ascertain whether the claims recite sufficient structure for performing the recited function and, if not, what corresponding structure is disclosed in the Specification. *See, e.g., Al-Site Corp. v. VSI Int'l, Inc.*, 174 F.3d 1308, 1318 (Fed. Cir. 1999) (the court considering whether to invoke a means plus function analysis when the claims did not recite "means for").

In *University of California*, the specification did not recite any corresponding structure, and so the functional claims were invalid where precedent constrained the analysis in that knowledge of the protein does not render obvious the cDNA. Presently, we do not reach the means analysis and avoid those aspects of *University of California* including the specific rule that the Office has chosen to apply because the Office need not inquire about corresponding structure in the specification. Sufficient characteristics describing the invention are present in the nonfunctional claims, so the *Al-Site* inquiry need not be made. The rule of *University of California*, to the extent it is not overruled or limited, need not be invoked to construe a means. The claims are definite and meet the written description requirement where the claims are fully supported and, further, possession is shown at least by the cultivar on deposit. Possession is further shown where the disclosure teaches precisely the selectable traits and other morphological traits of Enola (see entire disclosure).

The Office asserts that the Patent Owner has confused the requirements of 35 U.S.C. §112 ¶ 1 with those of ¶ 2 since the Patent Owner has discussed the claims and enablement in context of written description. Accordingly, the Office has refused to consider Bassett because this article pertains to enablement, where Bassett was submitted to show a level of skill in the art in accord with the *Moba* standard that the Office has also ignored, as discussed *supra*. This may reflect some confusion at the Office as well, since the separate requirements of enablement and written description are related and

intertwined:[12]

> The purpose of section 112, first paragraph, is to ensure that there is an adequate disclosure of the invention for which patent rights are sought. The purpose of the description requirement is to state what is needed to fulfill the enablement criteria. These requirements may be viewed separately, but they are intertwined.

Enzo Biochem and *Moba,* discussed *supra*, requires the written description/possession analysis to consider the nature of the relevant art. Bassett is evidence of maturity and advancement in the relevant art, which differs substantially from the use of cDNA. Here the Office has gone on record as refusing to consider Bassett (TAB 7), which is evidence to show an advanced state of the breeder selection art and sufficient skill to use the teaching of the Specification.

The Patent Owner asserts that the Office has not placed the written description rejection in context of the related art, and so there is no *prima facie* case in support of the written description rejection. Furthermore, to the extent that the Office may assert a *prima facie* case under *University of California*, it stands rebutted by evidence of record and other law distinguishing *University of California*. The showing of record is that the *Moba* test is fully met.

It is clear from *Lockwood* and *Moba*, discussed *supra*, that adherence to the written description requirement must be assessed from the standpoint of ordinary skill in the relevant art. The Office fails to consider the nature of the art and the level of skill in the art when it applies the narrow rule of *University of California*. In particular, *Moba* has identified a superceding test—one to assess possession from the perspective of ordinary skill in the art on the basis of the written description, including information obtainable from the deposits of the claimed sequences, subsequences, mutated variants and mixtures sufficient to demonstrate possession of the generic scope of the claims. Presently, where the germplasm for a *Phaseolus vulgaris* trait is of record, the breeder-growers are taught to make the selection based on particular features in the claims themselves, for example, by selecting a "yellow seed coat of from about 7.5 Y 8.5/4 to about 7.5 Y 8.5/6 in the Munsell

[12] *Kennecott Corp. v. Kyocera Int'l, Inc.*, 835 F.2d 1419, 1421, (Fed. Cir. 1987)

Book of Color when viewed in natural light."

To illustrate the nature of breeder-grower art and the level of ordinary skill at the time of filing, the Patent Owner submits herewith a publication, namely, Genetics Committee List of Genes – *Phaseolus vulgaris* L (TAB 8), which has been compiled by the Bean Improvement Committee—a volunteer membership association dedicated to bean genetics. The attachment is accessible from the BIC website at http://www.css.msu.edu/bic/ and was compiled with successive updates occurring in 1965, 1982, 1989, and 1993. The table itself is a comprehensive listing of all known *Phaseolus vulgaris* genes, but with two connotations where cDNA is usually denoted as a "structural gene" and where the other genotypes are denoted as selectable or crossable traits. It is the nature of breeder-grower art that germplasm properties or genotypes may be reduced to notation, such as *ace* to produce a shiny pod, or *Beg* that with *P* gives a begonia red flower color.

The Patent Owner has taught that the claimed yellow seed coat color is a selectable trait that can be used to select for highly desirable beans. What this means to those skilled in the art is that the selectable phenotype may be further selected and/or crossed with other phenotypes. A process of continuing selection as outlined in the Specification may be used in selection processes to produce more highly desirable beans. See, for example, the Abstract "[t]he invention also relates to a method for producing a field bean plant by crossing a first parent field bean plant with a second parent field bean plant, wherein the first and/or second field bean plant is the field bean plant of the present invention." This is what Bassett did. Conventional breeder-grower techniques that may be applied to make additional cultivars include, for example, crossing, selfing, backcrosses, hybrid breeding, and crosses to populations, as stated in column 4 at lines 38-46. The disclosure must be considered from the perspective of the art for what it teaches the skilled artisan.

The Office on page 8 of the current action finds that the Patent Owner has not provided compelling arguments for why the written description rejection is improper, nor evidence of possession. We traverse for two reasons. First, the Office has not established a *prima facie case* where reliance upon *University of California* to define the standard of the *prima facie case* is misplaced, and so it is not the Patent Owner's burden to come forth with

that evidence. Second, to the extent that a *prima facie* case is established, it is rebutted by relevant evidence the Office has refused to consider--evidence showing possession in context of the nature of the art and the level of ordinary skill. This is because the art is highly advanced where it has compiled a comprehensive list of genes and rules for the breeder use of such genes, and the level of skill in using Enola is particularly illustrated by Bassett.

We find additional reason to traverse the written description rejection. The test should be made from the perspective of ordinary skill;[13] however, the Office has applied *University of California* in a bright-line way where really there has been no assessment from the perspective of ordinary skill. The title of Bassett specifically acknowledges use or comparison of Enola germplasm, and is provided to show the level of skill. The Office deems Bassett irrelevant to written description and characterizes the Patent Owner's remarks as being directed towards enablement. The Office finds that the Patent Owner has not addressed the rejection of record because enablement arguments have been interspersed with the written description arguments, and so dismisses Bassett. The Office position fails to observe the perspective of ordinary skill:[14]

> Examiner reiterates that, as set forth in *University of California*, enablement and written description are independent requirements of 112 first paragraph. The instant rejection is a written description rejection.

Again, we remind the Office that the two requirements are separate and distinct, but also related and intertwined. We ask the Office to reverse its position and consider arguments and evidence which it now deems to be irrelevant and unworthy of consideration.

For these reasons we respectfully submit that the written description rejection cannot stand, and request it to be withdrawn.

14. Claim Rejections 35 U.S.C §112 First Paragraph Enablement

Claims 1-15, 51, 52 and 56-58 stand rejected under 35 U.S.C. §112, first paragraph,

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[13] *See Moba B.V.*, 325 F.3d at 1321, (the "possession" test requires the viewpoint of one of skill in the art.

[14] Office action of December 2, 2003, page 8.

for failure to comply with the enablement requirement. We respectfully traverse.

The Office cites *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) and identifies eight considerations found therein. The test for enablement is whether those of ordinary skill in the art must endure undue experimentation to practice the invention. Eight factors according to the *Wands* test include the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

The Office discusses a few of the *Wands* factors. Again, the Office does not analyze from the perspective of skill in the art. In *In re Wands*, the particular issue under consideration was the predictability of being able to make a particular monoclonal antibody. The Court stated:[15]

> Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not experimentation.

The Court further stated:[16]

> The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art. The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.

Based on the patent disclosure, the Office previously indicated allowability of certain claims in a prior office action; however, the Office now chooses to withdraw the indication of allowability on the basis of the Patent Owner's response filed 3/25/03. The Office asserts as a basis for this new rejection the fact that the disclosed cultivar is actually a variety of genetic entities having a range of sizes, shapes, and colors, both of seed coat and hilar ring. Evidence in support of this new rejection is said to include RFLP analysis as

[15] *Wands* at 1404.

[16] *Id.*

evidence of genetic diversity in individuals 1, 51, 52 and 53, as shown in the Declaration of Laura Conley. This is because the Office sees that the purpose of making a seed deposit is to provide "a reproducible means of making a genotypically and phenotypically unique plant that cannot be recreated based on a patent disclosure."[17] The Office again quotes the Specification to show that Enola is disclosed to have uniformity and stability. The Office finds that each sample of seed obtained from ATCC would consist of a different mixture of seed resulting in a different heterogeneous population of plants. We respectfully traverse.

The weight of evidence controverts the Office findings. Again, there is not the contradiction that the Office asserts. The Declaration of Gil Waibel confirms that Enola stably produces the disclosed phenotypes under sustained cultivation. The Office merely assumes that genetic variation within a cultivar necessarily results in non-uniform phenotypes; however, the purpose and result of breeder selection has successfully reinforced the Enola phenotypes for uniformity and persistence. The Declaration of Gil Waibel directly controverts the findings of the Office by showing an array of remarkably uniform traits or phenotypes persisting in seed from crop years 1996, 2000 and 2001. Enola is a cultivar having the disclosed characteristics.

The Office asserts a position that contradicts the MPEP. The purpose of seed deposit is *not* to provide a reproducible means of making a genetically and phenotypically unique plant that cannot be recreated based on a patent disclosure. MPEP §2402 addresses the issue of why deposits may be required:

> Where the invention involves a biological material and words alone cannot sufficiently describe how to make and use the invention in a reproducible manner, access to the biological material may be necessary for the satisfaction of the statutory mandates for patentability under 35 UI.S.C. §112.

MPEP §2402 differs from the position asserted by the Office. The deposit is provided to describe how to make and use the invention in reproducible manner. Nothing is said about the distinction of phenotypic and genotypic uniformity that the Office would require. However, Enola is reproducible because it does exhibit uniformity and stability as

[17] Office action dated December 2, 2003, page 13.

to the selected traits and other traits shown and described in the Specification, as confirmed by the Declaration of Gil Waibel. It is not inapposite to any purpose or requirement of law that the Patent Owner is claiming as it does, and we fail to see the contradiction asserted by the Office. The purpose of the deposit requirement is fulfilled as shown, even assuming (and here we make no admission) that words alone cannot sufficiently describe how to make and use the invention in a reproducible manner.

The Office finds that, even if the deposited seed represents a uniform cultivar, the Patent Owner has still failed to provide guidance for how to make other cultivars with the claimed characteristics. We disagree and respectfully traverse.

The disclosure is replete with guidance on how to make other cultivars. Enola may be crossed with other field bean plants (see Abstract, also column 1, lines 51-56). Selection may be made for individual plants according to segregated color, plants exhibiting small leaves, good adherence of the pod to branches of the plant, resistance to pod shattering, and greater than average yield (column 3, lines 9-13 and 16-22). Other traits may be used as selection traits or to confirm the phenotype, for example, leaf morphology, flower color, pod morphology at onset and maturity, seed color, seed shape and weight, anthocyanin pigmentation, resistance to heat and root rot, and date to maturity, all as described in Example 1. Similarly beneficial organoleptic qualities are described in column 4 at lines 18-30. A method of using is described in Example 2.

The germplasm to do this is inherent to the ATCC deposit (column 6 lines 12-13) and may be read into the disclosure by virtue of this inherency. Conventional breeder-grower techniques that may be applied to make additional cultivars include, for example, crossing, selfing, backcrosses, hybrid breeding, and crosses to populations, as stated in column 4 at lines 38-46. The disclosure must be considered from the perspective of the art for what it teaches the skilled artisan. For example, the specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well-known to those who are skilled and is already available to the public. *In re Bucher*, 929 F.2d 660, 661 (Fed. Cir. 1991).

The Office observes that the inventor asserts he had never seen yellow beans

before going to Mexico and is unaware of the sale of yellow seed in the United States, then finds:

> Hence, in the absence of the deposited seed, it is unclear how one of skill in the art can practice the claimed invention. Methods of plant breeding do not allow for the creation of a desired characteristic out of thin air. Hence it would appear that without a readily available source of germplasm containing the yellow seed coat characteristic, undue trial and error experimentation would be required to screen through the myriad *Phaseolus vulgaris* plants available in the world and progeny plants derived therefrom, to identify other field bean plants with the claimed characteristics. It is submitted that at best Patent Owner has only provided enablement for plants of the deposited Enola line or plants produced from the deposited Enola line of accession number 209549.

The Patent Owner's answer is twofold. First, the above argument is not applicable to the enablement rejection of claims addressing plants that are produced from the deposited Enola line of accession number 209549. This includes claims 1-7, which recite the deposit. Second, the Patent Owner has taught that the selectable traits may be used together with the techniques of crossing, selfing, backcrosses, hybrid breeding, and crosses to populations, to improve *Phaseolus vulgaris* using the germplasm on deposit. Further selection processes within the skill of the art may encourage additional traits and additional uniformity of known traits. Furthermore, the germplasm may be crossed as disclosed for similar beneficial purposes. The art does not view selectable traits as being linked to any one cultivar and recognizes that such traits may be crossed into other populations. For example, this is illustrated by Bassett and the aforementioned Genetics Committee List of Genes – *Phaseolus vulgaris* L, which identifies selectable genetic traits by virtue of interaction with other traits without limitation as to source of germplasm.

The level of experimentation that is required to practice the broader genus is not undue where it is within the demonstrated skill and ability of the art, where germplasm representative of the trait is on deposit of record, where the art views this as germplasm for a selectable and crossable trait of *Phaseolus vulgaris* (as distinct from a particular cultivar), and those of ordinary skill can work in an ordinary way that is not undue for this art to practice the invention.

Analysis under the *Wands* factors does support enablement. As to the genus

claims, e.g., claim 13 directed to the color feature, the *Wands* factors consider the quantity of experimentation necessary to obtain this color. The disclosure shows that the Patent Owner did this initially from a self-segregating population of selected beans and continued to refine the selection by ordinary processes (column 3 lines 3-29). Bassett tends to show a sufficient level of skill to duplicate these results from other cultivars, e.g., by crossing and selecting for color, and this work has resulted in Bassett proposing a new trait to the Bean Improvement Committee.

Wands considers the amount of direction or guidance presented. The disclosure shows that one plants the beans and selects from the growout according to selection processes found in column 3 at lines 3-29, as may be influenced by selecting to identify the morphology of Example 1. *Wands* considers the presence or absence of working examples of the invention, where there are Examples 1 (morphology) together with Example 2 (propagation) and a line of reasoning to cross, self, backcross, hybrid breed, or cross to populations by techniques within the ordinary skill (column 4 lines 38-46). *Wands* considers the nature of the invention. One plants the beans, grows them, and selects for traits that are taught by the Specification.

Wands considers the state of the prior art, where breeder-selection has been ongoing since ancient times. The advancement of the art and the level of skill are high, for example, as illustrated in the following passage from Bassett:

> For this paper, only a brief introduction to the genetics of seed coat color is needed. The cultivars tested in this paper all carried the dominant (wild type) allele at the *P, C, J, and Rk* loci, and those dominant alleles do not alter the color. Similarly, the cultivars tested all carried the recessive *r* allele at the *R* locus for dominant red color, which is closely linked to *C*. The genes *G, B, and V* are color modifying genes: *G* (from Gelbe, a German word) for yellow with *G b v, B* for mineral brown with *G B v*, and *V* for violet to black (anthocyanin pigments) with *G B V*. With *g b v,* the seedcoat is nearly colorless, chamois to (very) pale greenish yellow or cream color. This paper presents evidence [derived from use of Enola] for a ninth seedcoat color gene expressing SGY in the P[Cr]J g b v Rk genetic background.

Wands considers the relative skill of those in the art, which is illustrated by Bassett (TAB 6). The level of skill is high. *Wands* considers the predictability or unpredictability of the art, where there is merely a requirement to recognize the disclosed phenotype and

select for it. *Wands* considers the breadth of the claims, which is not undue when it is realized that the germplasm on deposit may be crossed to other populations and/or that Enola may be further improved by continuing selection.

Wands must be implemented in recognition of other law. The issue of whether or not undue experimentation is required must be decided on the facts of each case. Reported cases are of limited precedential value. *See, e.g., In re Angstadt,* 537 F.2d 498, 190 USPQ 214 (CCPA 1976); *In re Metcalfe*, 410 F.2d 1378, 161 USPQ 789 (CCPA 1969). It is well settled that patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art. *In re Vaeck, supra*; *In re Angstadt, supra* 537 F.2d at 502-03, 190 USPQ at 218. Id. at 1067.

The Office finds that the post-filing date Bassett article did not follow the teaching of the disclosure. Bassett does show "Enola" in the title. What Bassett did was attempt to identify what the parent germplasm of parent stock Enola might have been. By obtaining other sources of germplasm and crossing them with Enola, he succeeded in producing a mottled bean by crossing with the Enola deposit. These results were sufficient for him to propose a new SGY trait indicative of the Enola seed coat color. He concludes that Wagenaar could have been the parent stock, although Wagenaar is yellow (ventral) chamois (dorsal).

For the reasons explained above, we respectfully request withdrawal of the enablement rejection.

15. Indefiniteness

Claims 1-7, 10 and 57 stand rejected for indefiniteness under 35 U.S.C. §112, second paragraph. We respectfully traverse.

The Office asserts that the ATCC deposit is admittedly diverse, so that the metes and bounds of the claims are unclear. Fundamental to that finding is an incorrect assumption that Patent Owner has failed to define the seeds and plants that are encompassed by the claims because they are diverse and have so many phenotypes. The Office asserts that out of 2500 seeds on deposit where the seeds consist of multiple genotypes one would not know which ones infringe the claims and which ones do not.

The Office consistently returns to this issue of genotype. We do not necessarily agree or disagree that the cultivar contains a uniform genotype. There is evidence of genetic diversity within the Enola cultivar. On the other hand, the evidence of genetic diversity is not linked to diversity of phenotype or trait, and Enola expresses the selected and characteristic traits uniformly and stably. The Declaration of Gil Waibel confirms the properties of Enola on deposit to include stability and uniformity. One will know what materials infringe and which do not infringe by virtue of comparison to the detailed disclosure of plant morphology, as reflected in the unambiguous wording in the claims. As to the seeds on deposit there may be additional studies performed to show similarities with the overall cultivar, for example, as shown in the Declaration of Gil Waibel which was prepared for the express purpose of showing infringement.

For the reasons explained above, we respectfully request withdrawal of the enablement rejection.

16. Claim Rejections 35 U.S.C. §102/103

Claims 8-15, 51, 52, and 54-58 remain rejected under 35 U.S.C. §102(b) as being anticipated by or, in the alternative, under 35 U.S.C. §103(a) as being obvious over any of CIAT G13 094, G02 400, G22 215, G22 227, 622 230, G11 891 or Kaplan, or Hernandez-Xolocotzi et al. or Gepts.

The Office reaffirms the burden-shifting onto the Patent Owner establishing Patent Owner's obligation to test the beans. The principle for the burden shifting is that the Patent Owner is required to do what the Office is not equipped to do. However, it is inappropriate to shift that burden where neither the Office nor the Patent Owner can test beans that are unavailable. In other words, even if so equipped the Office could not test the beans because they are unavailable. Here the burden-shifting does not work. Some rule of reason must attach and the Office cannot shift the burden to the extent that the Office requires a task that is impossible. Also, to the extent that the principle of burden shifting is a principle at equity, it may be important to note that the Patent Owner is a small entity with three employees.

What has happened in context of the consolidated reexamination is that CIAT is the

party requesting reexamination. CIAT is a large entity with multinational connections. At the time of Patent Owner's last response, CIAT would not fulfill the Patent Owner's request to provide beans that the Office required the Patent Owner to test. Thus, the burden shifting became circular where the Patent Owner could not test the beans, which were under the control of the CIAT-requestor in the very reexamination they had commenced.

CIAT has now provided beans for testing. The Patent Owner is happy to do what it can, and to that end has now received and tested all of the beans that repositories were able to send. The attached Declaration of Polly Proctor (TAB 9) describes the results of such testing. G2400, G 118911, G13094, G22215, G22227, G22230, PI 282060, PI 312090, PI208777. This list includes specifically all of the CIAT beans still at issue in the rejection and other beans that were at issue at the time of Patent Owner's last response. It is noted that the Office has an apparent interest in these beans because CIAT cited these beans to the Office in the request for reexamination.

The Declaration of Polly Proctor accompanying this response shows the analytical results, which speak for themselves. The testing was performed under witness. The claimed color range of "from about 7.5 Y 8.5/4 to about 7.5 Y 8.5/6 in the Munsell Book of Color when viewed in natural light" patentably distinguishes all beans tested.

In fact, the test result colors were not even close. In the case of PI 208777 the beans scored red. These colors are not sufficiently close to the claims as to sustain the line of reasoning that the Office postulates for §103 suggestion. The Office postulates that variations in phenotype may occur as the result of different soils, environmental conditions, cultivation conditions and geographic conditions. This is not so much motivation as it is speculation about what effects environmental conditions may have upon phenotype. It will be appreciated that the Declaration of Gil Waibel represents growout data from seed spanning crop years 1996, 2000 and 2001. The beans under growout conditions encountered a variety of environmental and did not demonstrate the kind of variation as postulated by the Office. The results, especially the Enola seed coloration, did not appreciably vary. This evidence rebuts the Office assumption that phenotypes vary out of and/or into the color range, and so refutes the asserted motivation.

The matter is disposed by Bassett having proposed to the Bean Improvement Cooperative a new selectable trait or gene documented alternatively as *gy* or SGY following investigations into Enola. The *gy* submission confirms the novelty and nonobviousness of Enola coloration as claimed. Where Bassett—producing a mottled bean--has concluded that Wagenaar is the closest parent stock, another expert, Paul Gepts, has produced a Declaration on the basis of RFLP to conclude that the closest parentage is Peruano—a different cultivar.

The Office presently insists upon continuation of the burden shifting principle where the Patent Owner has challenged the credibility of statements made in the Reexamination request. This is because the Office finds that the merit of one prior art reference has no relevance to the merit of another prior art reference. We respectfully ask the Office to reconsider that position under these facts. In this case, CIAT has said to the Patent Office in a request for reexamination that the beans which CIAT has finally allowed Polly Proctor to test each constitute a prior art bar against the issued claims. Those statements by CIAT are now shown to be untrue by virtue of the test results. Analysis of the reexamination request will confirm that CIAT, which possessed the beans at the time of filing their request never reported test results on their own beans. Their credibility is at issue.

The Office has until now been entitled to accept the truth of statements on the face of the reexamination request. In this regard, by virtue of the burden-shifting, the Office has become a messenger of those untruthful statements. Therefore one of two things has happened. It seems that CIAT failed to exercise diligence by testing their own beans in preparing the reexamination request. If CIAT possessed such test results, perhaps they were intentionally withheld.

We are of the opinion that reexamination never would have commenced if the Commissioner had known of the falsehoods that CIAT asserted at the time of approving the reexamination request. The burden-shifting now underway places an immense burden upon the Patent Owner. It is essentially the burden of being denied essential materials to fulfill a burden that normally resides with the Office. That burden appears to be the result of poor diligence by the requestor CIAT. It is unsupported hyperbole, and so the burden

shifting cannot stand because there is no reasonable basis that it should continue.

The principle of burden-shifting is only appropriate so long as the Office has a "sound basis" for believing the products of the claims and those of the prior art are the same. *In re Spada* , 911 F.2d 705, 708, 15 USPQ2d 1817, 1655, 1658 (Fed. Cir. 1994) ("when the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not). It can no longer be the case where the PTO has "sound basis" when it has been required by circumstances to convey allegations that are now proven false. The Board has cautioned about the act of burden-shifting:[18]

> before an applicant can be put to this burdensome task, the examiner must provide some evidence or scientific reasoning to establish the reasonableness of the examiner's belief that the functional limitation is an inherent characteristic of the prior art.

At present, the only evidence or reasoning to establish the reasonableness of the examiner's belief is an assumption that the Office was once entitled to make, namely, that statements made in the reexamination request are true. Presently, the Patent Owner has duly made best efforts to comply with the request for burden-shifting and actually tested all of the beans found to be obtainable from repositories. The test results contradict the truth of statements made in the reexamination request, and so the reasoning to shift the burden is rebutted. Besides, the Patent Owner has met the duty by testing all of the beans that were found to be available from repositories.

It will be appreciated that Patent Owner has not tested Kaplan, Hernandez, Voysest, or Gepts. Neither has CIAT reported test results in making their request for reexamination. The Patent Owner requests that the burden be lifted and that the §102/103 rejections be withdrawn.

17. Information Assessment

The Office requires information in the Requirement For Information Under 37 C.F.R §1.105. The information is required to determine whether the field beans obtained in

[18] *Ex Parte Skinner*, 2 USPQ2d 1788 (Bd. Pat. App. 1986).

Mexico were in public use or on sale in the United States prior to the filing date of the instant patent.

The Patent Owner is filing herewith a full response to the Requirement including an additional Declaration of Larry Proctor (TAB 10) and associated documents including IDS (TAB 11). This is in addition to information already of record.

Conclusion

The Patent Owner has fully addressed the Examiner's concerns relating to the specifications and claims. The Patent Owner believes that no additonal fees are due. However, if fees are in fact deemed necessary in connection with this amendment, the Examiner is authorized to charge deposit account number 12-0600. Please call the undersigned with any questions.

Respectfully submitted,

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CERTIFICATE OF SERVICE
37 C.F.R. §1.248

The undersigned certifies that on June 2, 2004, a copy of the foregoing amendment including all attachments was mailed by first class mail bearing sufficient postage to:

Dr. John H. Dodds
Dodds & Associates
1707 N. St. NW
Washington, D.C. 20036

The attachments include those specified in the amendment, additionally including a Petition for Three Month Extension of Time, Transmittal, Fee transmittal, Certificate of Mailing, Request to amend attorney docket number, together with Information Disclosure Statement and cited references (TAB 1), PAIRS system printouts from application number 90/005,892 and 09/773,303 (TAB 2), Copies of Information Disclosure Statements previously filed in application numbers 09/773,303 and 90/005,892 (TAB 3); Reissue Declaration by the inventor (TAB 4); Printout from Hyperdictionary.com (TAB 5); Declaration of Gil Waibel (TAB 6); Bassett article (TAB 7); Bean Improvement Committee Comprehensive list of Genes (TAB 8); Declaration of Polly Proctor (TAB 9), and Declaration of Larry Proctor (TAB 10), and Information Disclosure Statement with cited references (TAB 11).

By Dan Cleveland, Jr.

June 2, 2004
Date

TABLE 1
SPECIFIC IDENTIFICATION OF ERROR
IN SUPPORT OF REISSUE DECLARATION AT TIME OF FILING

Claim	Identification of error
15. (New) Seed of claim 14 wherein the color of the hilar ring is from about 2.5 Y 9/4 to about 2.5 Y 9/6 in the Munsell Book of Color when viewed in natural light.	The applicant has a right to claim, in combination with the limitations of claims 14, that the color of the hilar ring is from about 2.5 Y 9/4 to about 2.5 Y 9/6 in the Munsell Book of Color when viewed in natural light.
16. (New) A *Phaseolus vulgaris* field bean plant, said plant comprising a wood-like stalk and a plurality of wrinkled, dull, ovate-shaped leaves.	The Patent Owner and Inventor have a right to claim a *Phaseolus vulgaris* field bean plant, said plant comprising a wood-like stalk and a plurality of wrinkled, dull, ovate-shaped leaves.
17. (New) The plant of claim 16, wherein said plant comprises a plurality of white flowers.	The Patent Owner and Inventor have a right to claim, in combination with the limitations of claim 16, wherein said plant comprises a plurality of white flowers.
18. (New) The plant of claim 16, wherein at least one of said flowers comprises a plurality of white wings.	The Patent Owner and Inventor have a right to claim, in combination with the limitations of claim 16, wherein at least one of said flowers comprises a plurality of white wings.
19. (New) The plant of claim 16, wherein at least one of said flowers	The Patent Owner and Inventor have a right to claim, in

comprises a white keel.	combination with the limitations of claim 16, wherein at least one of said flowers comprises a white keel.
20. (New) The plant of claim 16, wherein said plant comprises a plurality of pods whose positions on said plant are scattered.	The Patent Owner and Inventor have a right to claim, in combination with the limitations of claim 16, wherein said plant comprises a plurality of pods whose positions on said plant are scattered.
21. (New) The plant of claim 16, wherein said plant comprises a plurality of flowers and pods, said stalk, leaves, flowers and pods being free from anthocyanin.	The Patent Owner and Inventor have a right to claim, in combination with the limitations of claim 16, wherein said plant comprises a plurality of flowers and pods, said stalk, leaves, flowers and pods being free from anthocyanin.
22. (New) The plant of claim 16 wherein the apex of said leaves are acuminate and the base of said leaves is obtuse.	The Patent Owner and Inventor have a right to claim, in combination with the limitations of claim 16, wherein the apex of said leaves are acuminate and the base of said leaves is obtuse.
23. (New) The plant of claim 22, wherein the average height of said plant when mature is about 34.9 cm.	The Patent Owner and Inventor have a right to claim, in combination with the limitations of claim 22, wherein the average height of said plant when mature is about 34.9 cm.

24. (New) <u>The plant of claim 22, wherein said plant has lodging resistance through maturity and withstands wind and other climatic conditions.</u>	The Patent Owner and Inventor have a right to claim, in combination with the limitations of claim 22, wherein said plant has lodging resistance through maturity and withstands wind and other climatic conditions.
25. (New) <u>The plant of claim 22, wherein said plant establishes a long, deep-growing, wood-like taproot, a plurality of wood-like lateral roots, and a plurality of wood-like feeder roots.</u>	The Patent Owner and Inventor have a right to claim, in combination with the limitations of claim 22, wherein said plant establishes a long, deep-growing, wood-like taproot, a plurality of wood-like lateral roots, and a plurality of wood-like feeder roots.
26. (New) <u>The plant of claim 25, wherein said taproot is larger than at least one of said lateral roots, and at least one of said lateral roots is larger than said feeder roots.</u>	The Patent Owner and Inventor have a right to claim, in combination with the limitations of claim 25, wherein said taproot is larger than at least one of said lateral roots, and at least one of said lateral roots is larger than said feeder roots.
27. (New) <u>The plant of claim 25, wherein said taproot averages 1.O cm +/- in caliper size.</u>	The Patent Owner and Inventor have a right to claim, in combination with the limitations of claim 25, wherein said taproot averages 1.O cm +/- in caliper size.
28. (New) <u>A pod of a *Phaseolus vulgaris* field bean plant having, at onset, a solid</u>	The Patent Owner and Inventor have a right to claim a pod of a

green color pattern, wherein said color is about 5 GY 6/6 in the *Munsell Book of* Color when viewed in natural light.	*Phaseolus vulgaris* field bean plant having, at onset, a solid green color pattern, wherein said color is about 5 GY 6/6 in the *Munsell Book of* Color when viewed in natural light.
29. (New) The pod of claim 28, wherein said pod has a pear-shaped cross section.	The Patent Owner and Inventor have a right to claim, in combination with the limitations of claim 28, wherein said pod has a pear-shaped cross section
30. (New) The pod of claim 29, wherein the curvature of said pod is straight and the orientation of the beak of said pod is straight.	The Patent Owner and Inventor have a right to claim, in combination with the limitations of claim 29, wherein the curvature of said pod is straight and the orientation of the beak of said pod is straight.
31. (New) The pod of claim 30, wherein said pod has slight constrictions.	The Patent Owner and Inventor have a right to claim, in combination with the limitations of claim 30, wherein said pod has slight constrictions.
32. (New) A pod of a *Phaseolus vulgaris* field bean plant having, at maturity, a solid tan color pattern, wherein said color is about 5 Y 8.5/6 in the Munsell Book of Color when viewed in natural light.	The Patent Owner and Inventor have a right to claim a pod of a *Phaseolus vulgaris* field bean plant having, at maturity, a solid tan color pattern, wherein said color is about 5 Y 8.5/6 in the Munsell Book of Color when viewed in natural light.

33. (New) The pod of claim 32, wherein said pod has a pear-shaped cross section.	The Patent Owner and Inventor have a right to claim, in combination with the limitations of claim 32, wherein said pod has a pear-shaped cross section.
34. (New) The pod of claim 32, wherein said pod is slightly curved and the orientation of the beak of said pod is variable.	The Patent Owner and Inventor have a right to claim, in combination with the limitations of claim 32, wherein said pod is slightly curved and the orientation of the beak of said pod is variable.
35. (New) The pod of claim 32, wherein said pod has slight constrictions.	The Patent Owner and Inventor have a right to claim, in combination with the limitations of claim 32, wherein said pod has slight constrictions.
36. (New) The pod of claim 32, wherein the average beak length of said pod is 1.2cm.	The Patent Owner and Inventor have a right to claim, in combination with the limitations of claim 32, wherein the average beak length of said pod is 1.2cm.
37. (New) The pod of claim 32, wherein said pod comprises seeds and the number of said seeds per pod is approximately 3.1.	The Patent Owner and Inventor have a right to claim, in combination with the limitations of claim 32, wherein said pod comprises seeds and the number of said seeds per pod is approximately 3.1.
38. (New) A *Phaseolus vulgaris* field bean plant, said plant comprising a wood-like stalk, at least one pod, and a plurality of	The Patent Owner and Inventor have a right to claim a *Phaseolus vulgaris* field bean plant, said plant

wrinkled, dull, ovate-shaped leaves.	comprising a wood-like stalk, at least one pod, and a plurality of wrinkled, dull, ovate-shaped leaves.
39. (New) The plant of claim 38, wherein said pod has, at onset, a solid green color pattern, wherein said color is about 5 GY 6/6 in the Munsell Book of Color when viewed in the natural light.	The Patent Owner and Inventor have a right to claim, in combination with the limitations of claim 38, wherein said pod has, at onset, a solid green color pattern, wherein said color is about 5 GY 6/6 in the Munsell Book of Color when viewed in the natural light.
40. (New) The plant of claim 39, wherein said pod has a pear-shaped cross section.	The Patent Owner and Inventor have a right to claim, in combination with the limitations of claim 39, wherein said pod has a pear-shaped cross section.
41. (New) The plant of claim 40, wherein said pod is straight and the orientation of the beak of said pod is straight.	The Patent Owner and Inventor have a right to claim, in combination with the limitations of claim 40, wherein said pod is straight and the orientation of the beak of said pod is straight.
42. (New) The plant of claim 41, wherein said pod has slight constrictions.	The Patent Owner and Inventor have a right to claim, in combination with the limitations of claim 41, wherein said pod has slight constrictions.
43. (New) The plant of claim 38, wherein said pod has, at maturity, a solid tan color	The Patent Owner and Inventor have a right to claim, in

pattern, wherein said color is about 5 Y 8.5/6 in the *Munsell Book of Color* when viewed in natural light.	combination with the limitations of claim 38, wherein said pod has, at maturity, a solid tan color pattern, wherein said color is about 5 Y 8.5/6 in the *Munsell Book of Color* when viewed in natural light.
44. (New) The plant of claim 43, wherein said pod has a pear-shaped cross section.	The Patent Owner and Inventor have a right to claim, in combination with the limitations of claim 43, wherein said pod has a pear-shaped cross section
45. (New) The plant of claim 43, wherein said pod is slightly curved and the orientation of the beak of said pod is variable.	The Patent Owner and Inventor have a right to claim, in combination with the limitations of claim 43, wherein said pod is slightly curved and the orientation of the beak of said pod is variable.
46. (New) The plant of claim 43, wherein said pod has slight constrictions.	The Patent Owner and Inventor have a right to claim, in combination with the limitations of claim 43, wherein said pod has slight constrictions.
47. (New) The plant of claim 43, wherein the average beak length of said pod is 1.2 cm.	The Patent Owner and Inventor have a right to claim, in combination with the limitations of claim 43, wherein the average beak length of said pod is 1.2 cm.
48. (New) The plant of claim 43, wherein said pod comprises seeds and the number of said seeds per pod is approximately 3.1.	The Patent Owner and Inventor have a right to claim, in combination with the limitations of claim 43, wherein said pod

	comprises seeds and the number of said seeds per pod is approximately 3.1.
49. (New) A method of harvesting a *Phaseolus vulgaris* field bean plant, said method comprising the following steps:	The Patent Owner and Inventor have a right to claim A method of harvesting a *Phaseolus vulgaris* field bean plant, said method comprising the following steps:
a. knifing the plant;	a. knifing the plant;
b. placing the plant into a windrow;	b. placing the plant into a windrow;
c. allowing the plant to dry.	c. allowing the plant to dry.
50. (New) The method of claim 49 wherein said drying step is continued for approximately 5 to 8 days.	The Patent Owner and Inventor have a right to claim, in combination with the limitations of claim 50, wherein said drying step is continued for approximately 5 to 8 days.
51. (New) Seed from a field bean variety of *Phaseolus vulgaris* comprising a seed coat and a hilar ring wherein the seed coat color is from about 7.5 Y 8.5/4 to about 7.5 Y 8.5/6 in the *Munsell Book of Color* when viewed in natural light;	The Patent Owner and Inventor have a right to claim seed from a field bean variety of *Phaseolus vulgaris* comprising a seed coat and a hilar ring wherein the seed coat color is from about 7.5 Y 8.5/4 to about 7.5 Y 8.5/6 in the *Munsell Book of Color* when viewed in natural light;
the seed being stably reproducible to provide additional seed having the hilar ring and the seed coat color,	the seed being stably reproducible to provide additional seed having the hilar ring and the seed coat color,

the seed being produced by a process that includes isolating a population of seed by selection of the hilar ring and the seed coat color from seed products of a segregating population of plants.	the seed being produced by a process that includes isolating a population of seed by selection of the hilar ring and the seed coat color from seed products of a segregating population of plants.
52. (New) The seed of claim 51 wherein the hilar ring color is from about 2.5 Y 9/4 to about 2.5 Y 9/6 in the Munsell Book of Color when viewed in natural light.	The Patent Owner and Inventor have a right to claim, in combination with the limitations of claim 51, wherein the hilar ring color is from about 2.5 Y 9/4 to about 2.5 Y 9/6 in the Munsell Book of Color when viewed in natural light.
53. (New) A seed from a field bean variety of *Phaseolus vulgaris* comprising a seed coat and a hilar ring wherein the hilar ring color is from about 2.5 Y 9/4 to about 2.5 Y 9/6 in the *Munsell Book of Color* when viewed in natural light.	The Patent Owner and Inventor have a right to claim a seed from a field bean variety of *Phaseolus vulgaris* comprising a seed coat and a hilar ring wherein the hilar ring color is from about 2.5 Y 9/4 to about 2.5 Y 9/6 in the *Munsell Book of Color* when viewed in natural light.
54. (New) The seed of claim 51, wherein said seed, when eaten, has a smooth texture and pleasing taste.	The Patent Owner and Inventor have a right to claim, in combination with the limitations of claim 51, wherein said seed, when eaten, has a smooth texture and pleasing taste.
55. (New) The seed of claim 51, wherein said seed is able to take on a	The Patent Owner and Inventor have a right to claim, in

larger volume of water when soaked prior to cooking.	combination with the limitations of claim 51, wherein said seed is able to take on a larger volume of water when soaked prior to cooking.
56. (New) The seed of claim 51, wherein said seed germinates in an environment free of light.	The Patent Owner and Inventor have a right to claim, in combination with the limitations of claim 51, wherein said seed germinates in an environment free of light.
57. (New) The seed of claim 51, wherein said seed from the middle of a pod is cuboid in shape.	The Patent Owner and Inventor have a right to claim, in combination with the limitations of claim 51, wherein said seed from the middle of a pod is cuboid in shape.
58. (New) The seed of claim 51, wherein the dry seed weight is about 43 grams per 100 seeds adjusted to 12 percent moisture).	The Patent Owner and Inventor have a right to claim, in combination with the limitations of claim 51, wherein the dry seed weight is about 43 grams per 100 seeds adjusted to 12 percent moisture).